REMARKS

The Invention

The invention is directed to a library of viral vectors, wherein each member of the library comprises (i) a first heterologous DNA encoding a first gene product, wherein the first heterologous DNA is common to each member of the library of viral vectors, and (ii) a second heterologous DNA encoding an second gene product, wherein the second heterologous DNA varies between the members of the library of viral vectors.

The Pending Claims

Claims 1-12 are pending and are directed to the library of viral vectors.

Amendments to the Claims

Claims 13-53 have been cancelled as being directed to a non-elected invention. Applicants reserve the right to pursue any cancelled subject matter in a continuation, continuation-in-part, divisional, or other application. Cancellation of any subject matter should not be construed as abandonment of that subject matter. No new matter has been added by way of the amendments to the claims.

The Office Action

According to the Office, the Restriction Requirement and Election of Species of January 13, 2004, are final. Applicants have cancelled claims 13-53 as being directed to a non-elected invention. The Office has withdrawn claims 7-8 and 10-11 from consideration as being drawn to a non-elected species. Applicants note that, if and when the generic claim embracing the elected species is allowed, the nonelected species, if included in dependent claims incorporating all of the limitations of the generic claim, will no longer be withdrawn from consideration since they also would be fully embraced by the generic claim. M.P.E.P. § 809.02(c).

Claims 1, 2, and 4 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent 6,001,557 (Wilson et al.) ("the Wilson patent"). Claims 1, 2, and 4 also are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent 6,440,728 (McVey et al.) ("the McVey patent"). Claims 1-6, 9, and 12 are rejected under 35 U.S.C. § 103 as allegedly being obvious over the Wilson patent. Reconsideration of these rejections is respectfully requested.

Discussion of Rejection under 35 U.S.C. § 102(b)

Claims 1, 2, and 4 are rejected under Section 102(b) as allegedly being unpatentable over the Wilson patent. According to the Office, the Wilson patent discloses an adenoviral vector construct wherein the vector comprises a selected transgene under the control of a selected promoter and other conventional vector/plasmid regulatory components. The Office contends that the selected transgene represents the first gene product of the pending claims and the conventional vector/plasmid regulatory components represent the second gene product of the pending claims. This rejection is traversed for the reasons set forth below.

The Wilson patent pertains to a recombinant adenoviral production system and recombinant adenoviral vector produced therefrom. The adenoviral vector comprises a selected transgene. However, contrary to the assertion of the Office, the "conventional vector/plasmid regulatory components" do not constitute a second gene product. The Wilson patent describes conventional vector/plasmid regulatory components as elements necessary to drive expression of the transgene in a cell (col. 7, lines 55-64). The Wilson patent provides examples of suitable vector/plasmid regulatory components at col. 7, line 65, through col. 8, line 48, which include promoters and polyadenylation sequences. As is understood in the art, promoters and polyA sequences are not gene products, but rather are DNA sequences which control gene expression. The only other description in the Wilson patent of a viral vector is the helper virus of the recombinant adenoviral production system (e.g., col. 8, line 49, through col. 12, line 13). According to the Wilson patent, the helper virus can comprise a reporter minigene, i.e., a single heterologous DNA. There is no teaching or suggestion in the Wilson patent to construct a viral vector comprising a first heterologous DNA encoding a first gene product and a second heterologous DNA encoding a second gene product, much less a library of viral vectors wherein the second heterologous DNA varies between the members of the library of viral vectors. Accordingly, the Wilson patent does not teach or suggest the subject matter of pending claims 1, 2, and 4, and the rejection under Section 102(b) should be withdrawn.

Discussion of Rejection under 35 U.S.C. § 102(e)

Claims 1, 2, and 4 are rejected under Section 102(e) as allegedly being unpatentable over the McVey patent. According to the Office, the McVey patent discloses an adenoviral vector construct wherein the vector comprises a growth discrimination gene (a first gene product) and a negative selection gene (a second gene product), each of which are under the control of separate regulatory elements. While the McVey patent may describe an adenoviral vector comprising a first heterologous DNA encoding a first gene product and a second heterologous DNA encoding a second gene product, the McVey patent does not disclose a

library of such viral vectors wherein the first heterologous DNA is common to each member of the library of viral vectors and the second heterologous DNA varies between the members of the library of viral vectors, as required by pending claims 1, 2, and 4. Accordingly, the McVey patent does not anticipate each and every element of pending claims 1, 2, and 4, and the rejection under Section 102(e) should be withdrawn.

Discussion of Rejection under 35 U.S.C. § 103

Claims 1-6, 9, and 12 are rejected under Section 103 as allegedly being obvious in view of the Wilson patent. This rejection is traversed for the reasons set forth below.

According to the Office, the Wilson patent discloses an adenoviral construct wherein the vector comprises a selected transgene under control of a selected promoter and other conventional vector/plasmid regulatory components. The Office contends that the selected transgene represents the first gene product of the pending claims and the conventional vector/plasmid regulatory components represent the second gene product of the pending claims. The Office further contends that the features of the pending dependent claims are either inherently present in the composition of the Wilson patent or constitute obvious variations in parameters which are routinely modified in the art.

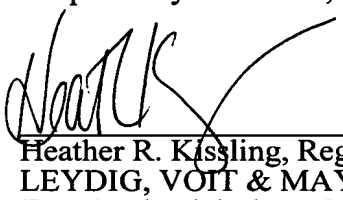
As set forth above, the Wilson patent does not disclose a library of viral vectors wherein each member of the library comprises (i) a first heterologous DNA encoding a first gene product, wherein the first heterologous DNA is common to each member of the library of viral vectors, and (ii) a second heterologous DNA encoding an second gene product, wherein the second heterologous DNA varies between the members of the library of viral vectors, i.e., the subject matter of pending claims 1-6, 9, and 12. The Wilson patent is directed to a recombinant adenoviral production system, not a library of viral vectors or use thereof. There is no suggestion in the Wilson patent to generate a library of viral vectors comprising a first heterologous DNA and a second heterologous DNA, much less a library of viral vectors wherein the second heterologous DNA varies between the members of the library. In that there is no teaching or suggestion of the library of viral vectors of pending claims 1-6, 9, or 12, the Wilson patent does not render obvious the subject matter of those claims and the rejection under Section 103 should be withdrawn.

Conclusion

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the

Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,



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